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10/780,339	02/17/2004	Hyesook Kim	3087.00013	1112

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EXAMINER	
DUNSTON, JENNIFER ANN	
ART UNIT	PAPER NUMBER
1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,339	KIM ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *22-25 and 32-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 26-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 June 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-34 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-21 and 26-31) in the reply filed on 10/10/2006 is acknowledged. The traversal is on the ground(s) that all three groups of claims related to screening for detection of effects of chemicals on gene expression and that groups I and III are both classified in class 435, subclass 6 and thus it would not be a burden to search all claims. This is not found persuasive because Group I is drawn to a device for detecting the effects of chemicals on gene expression, and Group III is drawn to a method of enabling the transfer of DNA to a membrane following gel electrophoresis. Thus, Groups I and II require separate searches of the patent and non-patent literature with different search queries required for each group. A reference that discloses the invention of Group I will not necessarily disclose the invention of Group III. Moreover, Group II is separately classified from Group I and requires separate searches of the patent and non-patent literature. Accordingly, the search of more than Group I would impose a serious search burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 22-25 and 32-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/10/2006.

An examination on the merits of claims 1-21 and 26-31 follows.

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. 60/448,266, filed 2/17/2003. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). In the instant case, the reference to the prior application is located below the statement of government support. Applicant is required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to place the reference to the prior application in the first sentence(s) of the specification. See MPEP § 201.11.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: panel 1D is not described in the Description of the Drawings section of the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because the description of Figure 2 refers to the color red, which cannot be seen in the black and white drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. Alternatively, the description of the drawings could be amended to completely describe the figures without reference to color. The objection to the drawings will not be held in abeyance.

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable

drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 37, line 31.

The disclosure is objected to because of the following informalities: the word "of" is misspelled at page 8, line 11. Appropriate correction is required.

The use of the trademarks GENETAC (page 16, line 14) and GENEPIX 4000 (page 15, line 15) have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16 and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8-9 and 12-13 of copending Application No. 10/593,412 (hereinafter the '412 application).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Instant claims 16 and 17 are drawn to a microarray screen. The structure of the microarray is not specified by the claims. Given the broadest reasonable interpretation, the claim encompasses nucleic acid microarrays and antibody microarrays. The conflicting claims are drawn to an antibody microarray screen comprising a substrate, monoclonal and polyclonal antibodies, and fluids unprocessed for immunoglobulin isolation (claims 1, 8 and 12). Further, the claims are drawn to microarray screens where the antibodies detect drug-metabolizing enzymes (claims 2-4, 9 and 13). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 16 and 17 are generic to all that is recited in claims 1-4, 8-9 and 12-13 of the '412 application. That is, claims 1-4, 8-9 and 12-13 of the '412 application fall entirely with the scope of claims 16 and 17 of the instant application or, in other words, instant claims 16 and 17 are anticipated by claims 1-4, 8-9 and 12-13 of the '412 application. Specifically, the microarray of the '412 application is encompassed by instant claims 16 and 17. The instant claims do not specify a structure for the microarray and both microarrays are capable of being used for the purpose of detecting and measuring the effects of chemicals on gene expression in animal cleavage stage embryos.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 and 26-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to "a screen." The instant specification defines the term "screen" to be any device capable of screening for gene expression in an embryo (page 8, lines 11-13). The device of claim 1 comprises animal cleavage stage embryos and a detecting means for detecting changes in gene expression. The claim does not provide a functional or structural relationship between the embryo and the detecting means. It is unclear how the two elements are related within a single device. The specification does not provide clarity in that the device used in the instant specification is a microarray containing cDNA sequences (e.g. page 14). The microarray of the instant specification is not brought into physical contact with the embryos. Rather, RNA is isolated from the embryos and subsequently hybridized to the microarray (e.g. pages 14-15). In light of the specification, it appears as though the claims are drawn to a collection of items rather than a single device. Therefore, the metes and bounds of the claimed device or screen are unclear.

Claims 2-6 depend from claim 1 and thus are indefinite for the same reasons applied to claim 1.

Claim 7 is drawn to a "screen." The instant specification defines the term "screen" to be any device capable of screening for gene expression in an embryo (page 8, lines 11-13). The device of claim 7 comprises animal cleavage stage embryos. It is unclear how the animal cleavage stage embryos are a device capable of screening for gene expression. The specification does not provide clarity in that the device used in the instant specification is a microarray

containing cDNA sequences (e.g. page 14). The microarray of the instant specification is not brought into physical contact with the embryos. Rather, RNA is isolated from the embryos and subsequently hybridized to the microarray (e.g. pages 14-15). In light of the specification, it appears as though the claims are drawn to animal cleavage stage embryos that could be used as starting material for a method of screening for gene expression. Therefore, the metes and bounds of the claimed device or screen are unclear.

Claims 8-15 depend from claim 7 and thus are indefinite for the same reasons applied to claim 7.

Claim 26 is drawn to a "screen." The instant specification defines the term "screen" to be any device capable of screening for gene expression in an embryo (page 8, lines 11-13). The device of claim 26 comprises animal embryos undergoing cleavage and neurulation. It is unclear how the two stages of animal embryos are a device capable of screening for gene expression. The specification does not provide clarity in that the device used in the instant specification is a microarray containing cDNA sequences (e.g. page 14). The microarray of the instant specification is not brought into physical contact with the embryos. Rather, RNA is isolated from the embryos and subsequently hybridized to the microarray (e.g. pages 14-15). Further, RNA is isolated separately from embryos undergoing cleavage and embryos undergoing neurulation (e.g. pages 14-15). In light of the specification, it appears as though the claims are drawn to separate groups of animal embryos that could be used as starting material for a method of screening for gene expression. Therefore, the metes and bounds of the claimed device or screen are unclear.

Claims 27-31 depend from claim 7 and thus are indefinite for the same reasons applied to claim 26.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 and 26-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a microarray device for detecting the effect of a chemical on gene expression, does not reasonably provide enablement for any other device, especially a device containing an animal embryo of any kind. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: Claims 1-6 are drawn to a screen comprising an animal cleavage stage embryo and a detecting means for detecting changes in gene expression. The instant specification defines the term "screen" to be any device capable of screening for gene expression in an embryo (page 8, lines 11-13). The specification provides microarray as an example (page 8, lines 11-13). Regarding the "detecting means for detecting changes in gene expression" of

claims 1-6, the instant specification discloses a microarray as such means (e.g., page 14). Thus, the claims are drawn to a device comprising an animal cleavage stage embryo and a detecting means such as a microarray. The nature of the invention is complex in that the device must comprise both the embryo and the detecting means and be capable of detecting the affects of chemicals on gene expression.

Claims 7-15 are drawn to a screen comprising animal cleavage stage embryos. The instant specification defines the term "screen" to be any device capable of screening for gene expression in an embryo (page 8, lines 11-13). The specification provides microarray as an example (page 8, lines 11-13). The nature of the invention is complex in that the presence of cleavage stage embryos in the device must allow one to identify and characterize chemicals as toxicants based on the effect of the chemical on gene expression, yet the device does not necessarily contain a component that allows for measurement of gene expression.

Claims 26-31 are drawn to a screen comprising animal embryos undergoing cleavage and neurulation. The instant specification defines the term "screen" to be any device capable of screening for gene expression in an embryo (page 8, lines 11-13). The specification provides microarray as an example (page 8, lines 11-13). The nature of the invention is complex in that the presence of embryos undergoing cleavage and neurulation in the device must allow one to identify and characterize chemicals as toxicants based on the effect of the chemical on gene expression, yet the device does not necessarily contain a component that allows for measurement of gene expression.

Breadth of the claims: The claims are broad in that they encompass devices capable of detecting changes in gene expression at the level of protein or mRNA. Further, the claims are

broad in that they encompass devices capable of detecting changes in gene expression relevant to the effects of chemicals in any species of organism. Moreover, the claims are broad in that no specific structures are specified for the detection of such changes. The claims encompass every possible structure for carrying out the intended use. The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims.

Guidance of the specification and existence of working examples: The specification envisions using animal cleavage stage embryos or embryos undergoing neurulation to screen for detecting and identifying chemicals that affect gene expression as an indicator of toxicity (e.g. paragraph bridging pages 1-2; paragraph bridging pages 6-7).

The specification defines the term "screen" as any device capable of screening for gene expression in an embryo (page 8, lines 11-12). The specification provides microarray as an example of a "screen." The specification defines the term "embryo" as any animal embryo (page 8, line 19). The instant specification discloses the use of the *Xenopus laevis* species because it is a facile model to investigate developmental toxicity (e.g. page 10, lines 16-20). With regard to a device, the specification discloses a microarray of about 1200 EST clones (e.g. page 10, line 19 to page 11, line 19; page 14, lines 3-21). With regard to other species of embryos, the specification teaches the hybridization of RNA isolated from the North American frog *Rana pipiens* to evaluate the use of the *Xenopus laevis* cDNA microarray for other species (e.g. page 13, lines 19-23). The specification asserts that because cross hybridization occurred with *Rana pipiens* liver RNA, the *Xenopus* microarray can be used for other frog species (e.g. page 13, lines 19-23).

The specification does not teach how to make and use a device comprising an animal embryo. The specification teaches the isolation of RNA from embryos, processing of the RNA to make labeled probes, and hybridization of the labeled probes to the microarray (e.g. page 14, line 22 to page 17, line 6). Thus, the embryo and microarray do not compose a device. Each component is handled separately with the embryo being treated as a source of RNA and the microarray being used as a device to measure gene expression (e.g. page 17, lines 7-29).

Predictability and state of the art: The prior art teaches the use of microarrays to measure changes in gene expression (for example, Altmann et al. Developmental Biology, Vol. 236, pages 64-75, 2001; Hemmati-Brivanlou et al, US Patent Application Publication No. 2002/0081610 A1; and Herwig et al (Nucleic Acids Research, Vol. 29, No. 23, page e117, 2001). The prior art appears to be silent with regard to a device comprising an embryo and a means for detecting gene expression such as a microarray. At the time the invention was made, the state of the art was underdeveloped. Accordingly, specific guidance is what is required for one to make and use the claimed devices.

Amount of experimentation necessary: The quantity of experimentation is large as one could not rely on the teachings of the instant specification or specification to make and use the claimed invention. It would require a large amount of inventive effort to make and use the claimed device. This type of experimentation is not routine in the art.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the underdeveloped state of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention.

Therefore, claims 1-15 and 26-31 are not considered to be fully enabled by the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-21 and 26-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Altmann et al (Developmental Biology, Vol. 236, pages 64-75, 2001; see the entire reference).

Claims 1-15 and 26-29 are drawn to "a screen." The instant specification defines the term "screen" to be any device capable of screening for gene expression in an embryo (page 8, lines 11-13). The specification provides microarray as an example. Claims 7-15 are specifically drawn to a microarray screen (i.e., microarray device). Regarding the "detecting means for detecting changes in gene expression" of claims 1-6, the instant specification discloses a microarray as such means (e.g., page 14).

Regarding claims 1-6, Altmann et al teach *Xenopus laevis* cleavage stage embryos and a microarray comprising cDNA (e.g. Title; page 65, prototype microarray preparation; pages 67-68, Scanning and Data Analysis; page 69, left column, 2nd full paragraph). The cleavage stage

embryos and microarray taught by Altmann et al would be capable of being used for detecting the effects of chemicals on gene expression.

Regarding claims 7-15, Altmann et al teach *Xenopus laevis* cleavage stage embryos (e.g. Title; page 69, left column, 2nd full paragraph). The cleavage stage embryos taught by Altmann et al would be capable of being used to characterize chemicals as toxicants based on the effect of the chemical on gene expression.

Regarding claims 16-21, Altmann et al teach a microarray device comprising cDNA (e.g. page 65, prototype microarray preparation; pages 67-68, Scanning and Data Analysis). The microarray taught by Altmann et al would be capable of being used for detecting and measuring the effects of chemicals on gene expression in cleavage stage embryos.

Regarding claims 26-31, Altmann et al teach *Xenopus laevis* cleavage stage embryos and embryos undergoing neurulation (e.g. Title; page 69, left column, 2nd full paragraph; Figure 3). The embryos taught by Altmann et al would be capable of being used for identifying and characterizing chemicals as toxicants based on the effect of the chemical on gene expression.

Claims 1-21 and 26-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Hemmati-Brivanlou et al (US Patent Application Publication No. 2002/0081610 A1; see the entire reference).

Claims 1-15 and 26-29 are drawn to "a screen." The instant specification defines the term "screen" to be any device capable of screening for gene expression in an embryo (page 8, lines 11-13). The specification provides microarray as an example. Claims 7-15 are specifically drawn to a microarray screen (i.e., microarray device). Regarding the "detecting means for

detecting changes in gene expression" of claims 1-6, the instant specification discloses a microarray as such means (e.g., page 14).

Regarding claims 1-6, Hemmati-Brivanlou et al teach microarrays containing *Xenopus laevis* embryonic gene sequences (e.g. Abstract; paragraphs [0006], [0066]-[0083]). The microarray taught by Hemmati-Brivanlou et al would be capable of being used for detecting the effects of chemicals on gene expression (e.g. paragraphs [0098]-[0102]). Further, Hemmati-Brivanlou et al teach cleavage stage *Xenopus laevis* embryos (stage 6) (e.g. paragraph [0119]).

Regarding claims 7-15, Hemmati-Brivanlou et al teach cleavage stage *Xenopus laevis* embryos (stage 6) (e.g. paragraph [0119]). The cleavage stage embryos taught by Hemmati-Brivanlou et al would be capable of being used to characterize chemicals as toxicants based on the effect of the chemical on gene expression.

Regarding claims 16-21, Hemmati-Brivanlou et al teach microarrays containing *Xenopus laevis* embryonic gene sequences (e.g. Abstract; paragraphs [0006], [0066]-[0083]). The microarray taught by Hemmati-Brivanlou et al would be capable of being used for detecting the effects of chemicals on gene expression (e.g. paragraphs [0098]-[0102]).

Regarding claims 26-31, Hemmati-Brivanlou et al teach cleavage stage (stage 6) and neurula stage *Xenopus laevis* embryos (stage 6) (e.g. paragraph [0119] and Figure 2). The embryos taught by Hemmati-Brivanlou et al would be capable of being used to characterize chemicals as toxicants based on the effect of the chemical on gene expression.

Claims 7-9 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Herwig et al (Nucleic Acids Research, Vol. 29, No. 23, page e117, 2001; see the entire reference).

Claims 7-9 and 13-15 are specifically drawn to a microarray screen (i.e., microarray device).

Regarding claims 7-9 and 13-15, Herwig et al teach a microarray containing zebrafish cDNA clones selected from a representative cDNA library from zebrafish gastrula stage embryos (e.g. page 1/9, right column, last paragraph; page 2/9, cDNA clone array design).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston, Ph.D.
Examiner
Art Unit 1636

jad

CELINE QIAN, PH.D.
PRIMARY EXAMINER